DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC-2022-0003]

Draft Policy Statement for Biosafety Level 4 (BSL-4) and Animal BSL-4 (ABSL-4) Laboratory Verification; Notice of Availability

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain comment on a draft policy statement regarding Biosafety Level 4 (BSL-4)/Animal Biosafety Level 4 (ABSL-4) verification requirements. The policy statement, once finalized, will assist individuals and entities in verifying that the facility design parameters and operational procedures, including heating, ventilation, and air conditioning (HVAC) systems, in BSL-4 and/or ABLS-4 laboratories are functioning as intended to meet the biosafety sufficiency requirement in the HHS/CDC select agent regulations.

DATES: Submit written or electronic comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0003, by either of the following methods.

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop H21-7, Atlanta, Georgia 30329.

Instructions: All submissions received must include the Agency name and Docket No. CDC-2022-0003. All relevant comments received will be posted without change to http://www.regulations.gov, including any personal information provided. **Do not send comments by email. CDC does not accept comments by email.**

Docket Access: For access to the docket to read background documents or comments received, or to download an electronic version of the draft policy statement, go to http://www.regulations.gov. Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop H21-7, Atlanta, Georgia 30329. Telephone: (404) 718-2000.

SUPPLEMENTARY INFORMATION:

A. Legal Authority

HHS/CDC is issuing this draft policy under the authority of sections 201–204 and 221 of Title II of Public Law 107-

188, (42 U.S.C. 262a).

B. Background

For entities that possess select agents and toxins, the HHS select agent and toxin regulations (42 CFR part 73) require that "biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards)" (42 CFR 73.12(b)). BSL-4 and ABSL-4 laboratory facility specifications and operational procedures are used for work with dangerous and exotic biological agents that could easily be aerosol transmitted within the laboratory, cause severe to fatal disease in humans, and typically do not have available vaccines or treatments. Therefore, these laboratories must implement and maintain the highest level of biosafety precautions for containment.

HHS/CDC reviews how entities that maintain BSL-4 and/or ABSL-4 laboratories have verified that the design and operational parameters, including HVAC, are functioning properly when determining if entities have met the sufficiency requirement in section 12(b) of the HHS select agent and toxin regulations. In developing a biosafety plan, an individual or entity should consider requirements found in the *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (42 CFR 73.12(c)). HHS/CDC has developed a draft policy statement for

BSL-4 and ABSL-4 laboratory verification based on the standards found in the 6th edition of the BMBL:

- BSL-4 D16(a): The ventilation system is designed to maintain the laboratory at negative pressure to surrounding areas and to provide differential pressure or directional airflow as appropriate between adjacent areas within the laboratory.
- ABSL-4 D16(a): The supply and exhaust components of the ventilation system are designed to maintain the ABSL-4 facility at negative pressure to surrounding areas and to provide differential pressure or directional airflow as appropriate between adjacent areas within the facility.
- BSL-4 D20: The facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.
- ABSL-4 D21: The ABSL-4 facility design parameters and operational procedures are documented. The facility is tested to verify that the design and operational parameters have been met prior to operation. Facilities are also re-tested annually or after significant modification to ensure operational parameters are maintained. Verification criteria are modified, as necessary, by operational experience.

HHS/CDC is requesting public comment on a draft policy statement on BSL-4/ABSL-4 laboratory verifications standards, including HVAC, to aid individuals and entities in verifying that these laboratories are properly functioning. We are making this policy document available to the public in the Supplementary Materials tab of the docket at www.regulations.gov for review and comment. All comments, such as items related to the appropriate acceptance criteria used to ensure systems are functioning as intended and documentation to demonstrate the sufficiency requirement has been met, that we receive on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be carefully reviewed and considered.

Dated: January 13, 2022.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

[FR Doc. 2022-00928 Filed: 1/18/2022 8:45 am; Publication Date: 1/19/2022]